

**REMARKS**

Reconsideration of the present application is respectfully requested.

**I. Status of Claims**

Claims 1-176 are hereby cancelled without prejudice or disclaimer. New claims 177-181 are currently presented. New claims 177-181 have been added to reflect preferred amino acid embodiments of original claim 91, as well as the pharmaceutical composition, medication, and methods thereof. New claim 177 recites the embodiment of original claim 91, with the inclusion of Markush groups for the various claimed amino acids. Additionally, new claim 177 has been amended to further define the scope of the claim to remove “not less than” as a claim limitation. As such, new claim 177 is directed to 4-mers, 5-mers, and 6-mers. Support for these new claims is found in original claims 91, 117, 118, 123, and 124 and throughout the specification as filed. No new matter has been added by way of this amendment.

For the Examiner’s reference, applicants provide the following table to clarify support for the new claims.

New Claim	Support
177	Original claim 91
178	Original claim 124
179	Original claim 117
180	Original claim 118
181	Original claim 123

**II. Telephone Conference**

Applicants respectfully thank the Examiner for his time during the conference call on December 5, 2005 to discuss the rejections and formalities of the Final Office Action. Applicants also thank the Examiner for the courtesy call on December 7, 2005 regarding the affirmation of the outstanding rejections.

While applicants understand that the Examiner's basis for the withdrawal of claims 172-175 is compliance with species election and Markush claim practice (MPEP 803.02), applicants respectfully disagree for the record with this basis for the further withdrawal of claims 117 and 124.

### **III. Claim Objections**

In the Final Office Action, the Examiner objected to claims 91 and 173 for grammatical errors. Applicants have addressed the claim objections in corresponding new claim 177. Specifically, applicants have removed the term "arbitrary", corrected the spelling of "proline", and removed the superfluous parentheses in the claim. Applicants submit that all claim objections have been overcome.

### **IV. 35 U.S.C. § 112, ¶1**

#### Written Description

Claims 91, 117, 118, 124, and 172-176 stand rejected as allegedly failing to comply with the written description requirement under 35 U.S.C. § 112, ¶1. According to the Examiner, the claims are directed to subject matter which is not supported by the specification in such a way that conveys possession of the invention. The Examiner summarizes his position with respect to the various factors considered in the written description requirement including the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a correlation between structure and function, and the method of making the claimed invention.

Applicants respectfully traverse the rejection, and request reconsideration. Applicants address the rejections with respect to the new corresponding claims 177-181.

Regarding the level of skill in art, applicants take no issue with the Examiner's statement that the methods involved are generally known in the art.

Regarding the partial structure, the Examiner believes that the structure of all compounds embraced by the invention are not sufficiently described. However, applicants respectfully submit



provided for making species of the claimed invention. Applicants respectfully submit that at least five exemplary methods of making the compounds are disclosed. Support for these exemplary methods is found in Examples 1, 9, 25, 40, and 58. Also within and following each of these examples are numerous exemplary species presented as Examples 1 through 86. Thus, the specification provides a representative number of species. Accordingly, there is ample support to show possession and overcome the written description rejection.

### Enablement

Claims 117, 118 and 124 stand further rejected for alleged lack of enablement. Specifically, the Examiner states that the specification, while enabling for making compounds of the examples, does not reasonably enable the methods of making pharmaceuticals, medicines or diagnostics for the compounds in the generic claims. The Examiner relies on factors described in *In re Wands* (858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)) to support his argument that undue experimentation would be required when looking to the nature of the invention, the breadth of the claims, the state of the prior art, the predictability of the art, the relative skill of those in the art, the amount of guidance presented, the presence/absence of working examples, and the quantity of experimentation necessary. According to the Examiner, claims to a compound with substituted amino acids are not enabled since the effect of amino acid substitution is an “unpredictable” art requiring extensive and undue experimentation. To support his contention, the Examiner provided articles or abstracts which describe technical caveats associated with amino acid substitution (Voet et al., Smilek et al., and Messer et al.).

Applicants respectfully submit that the cited references appear to be inapplicable here, in view of the new claims and the assays and working examples set forth in the specification. The Court of Appeals for the Federal Circuit interpreted the test for compliance with the enablement requirement as:

whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.

Claims 91, 118, and 176 stand rejected as anticipated by U.S. Patent No. 4,440,678 (to Svendsen) in view of Bastin (Org. Proc. Res. Dev. 2000, 4:427-435). According to the Examiner,

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Svendensen teaches H-Gly-Arg-MCA•2HBr, and teaches that the compound is used for enzyme assays, and thus inherently is a diagnostic. The Examiner then relies on Bastin for the teaching that HBr is a pharmaceutically acceptable salt. Thus, the Examiner asserts that the claimed invention is anticipated by the cited art.

Applicants respectfully traverse the rejection and request reconsideration. The present invention is directed to compounds with a 4-mer to 6-mer peptide chain. The cited art, however, teaches tripeptide derivatives, none of which are within the scope of the presently claimed invention. Therefore, the claimed invention is not anticipated by the cited art. Applicants request withdrawal of the rejection.

## VII. Conclusion

In view of the above amendments and remarks, the claims now presented are believed to in condition for allowance and such action is earnestly solicited.

If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Dated: December 13, 2005

Respectfully submitted,

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